

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 61, 62, 65, and 66 are currently pending and under consideration.

Response to Advisory Action

In the Advisory Action mailed September 15, 2004, the Examiner indicated that the Response filed August 24, 2004 failed to place the application in condition for allowance, because the arguments were based upon the Declaration of Dr. Fanger, which was not executed, and because there was no sufficient reason why the Declaration of Dr. Fanger was not submitted earlier.

Applicants respectfully submit that an executed copy of the Declaration of Dr. Fanger was submitted via facsimile on September 10, 2004, shortly after submission of the Response on August 24, 2004. As it appears that the executed Declaration of Dr. Fanger was not received prior to the mailing of the present Advisory Action, Applicants have enclosed herewith a further copy of the executed Declaration of Dr. Fanger, as well as a copy of the confirmation of receipt of the facsimile received from the U.S.P.T.O.

Regarding the timing of the submission of the Declaration of Dr. Fanger (as well as the accompanying Declaration of Dr. Henderson), Applicants respectfully submit that the Declarations were not previously submitted for the mere reason that Applicants did not believe it necessary in light of the evidence and arguments previously presented, demonstrating the overexpression of L552S polypeptides in lung cancer tissue and thereby establishing their utility in a variety of applications, including, *e.g.*, detecting lung tumors. Nonetheless, in light of the Examiner maintaining the rejection under 35 U.S.C. §101 in the Final Office Action mailed May 28, 2004, Applicants submitted the Declarations in response, as additional supporting evidence further establishing that the claimed invention possesses substantial and credible utility.

Applicants respectfully request that the Examiner favorably reconsider the instant application in light of the Declarations and remarks submitted below.

Rejection Under 35 U.S.C. §§ 101 and 112, First Paragraph

Claims 61, 62, 65, and 66 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, on the alleged basis that the claimed invention lacks a patentable utility. More specifically, the Examiner alleges that there is no evidence in the disclosure that polypeptides of SEQ ID NO:786 are overexpressed in lung tumor tissue and maintains the position that there is no direct linkage between the expression levels of a cDNA and its encoded polypeptide.

Applicants respectfully traverse this ground of rejection and submit that the specification clearly establishes specific, substantial, and credible utilities of the claimed invention. More specifically, Applicants submit that the skilled artisan would readily appreciate that the claimed L552S polypeptides are useful, for example, in the detection of lung cancer.

First, Applicants submit that the skilled artisan would appreciate that L552S polypeptides of SEQ ID NO:786 are overexpressed in lung cancer, based upon the data demonstrating that L552S polynucleotides are overexpressed in lung cancer, as discussed in detail in previous amendments submitted in this case. However, in further support of this assertion, Applicants have submitted with this response the Declaration of Gary Fanger, Ph.D. (the "Fanger Declaration"). The Fanger Declaration presents data obtained from immunohistochemistry analyses using anti-L552S antibodies and clearly confirms that L552S polypeptides are overexpressed in lung cancer as compared to normal lung tissue. Accordingly, Applicants would understand that lung cancer may be diagnosed by detecting L552S overexpression, *e.g.*, using antibodies generated against the polypeptide of SEQ ID NO:786.

Applicants submit that the skilled artisan would appreciate that variants of L552S polypeptides, to the extent they share common antigenic epitopes with L552S polypeptides, may be used in the detection of lung cancer, *e.g.*, to detect circulating L552S antibodies in lung tumor patients and/or produce antibodies specific for L552S, which may be used to detect L552S overexpression associated with lung tumors. Furthermore, Applicants submit that this utility exists even if an L552S variant, itself, is not overexpressed in lung cancer, since antibodies directed against any form of L552S would bind to other L552S polypeptides sharing at least one antigenic epitope and, therefore, be useful in detecting L552S polypeptide overexpression, which correlates with lung cancer, as described in the Fanger Declaration.

This being understood, Applicants further submit that the sequences of the L552S polypeptides share significant sequence homology, including common antigenic epitopes, as demonstrated by the accompanying copy of the Declaration of Robert Henderson, Ph.D. (the "Henderson Declaration"), which was previously submitted and made of record in copending U.S. Patent Application Serial No. 09/589,184. The Henderson Declaration establishes that lung cancer patients produce L552S-specific antibodies directed to at least one epitope present in the polypeptide of SEQ ID NO:786, which epitope corresponds to amino acid residues 21-40 in the polypeptide encoded by SEQ ID NO:790 (SEQ ID NO:791) and residues 15-34 in the polypeptide of SEQ ID NO:786, as shown in the sequence alignment submitted herewith for the Examiner's convenience. Accordingly, the polypeptide of SEQ ID NO:786, or a fragment thereof, may be used in the detection of lung cancer, *e.g.*, to detect circulating L552S antibodies and/or to generate antibodies specific for L552S, which may be used to detect L552S overexpression and, thus, lung cancer.

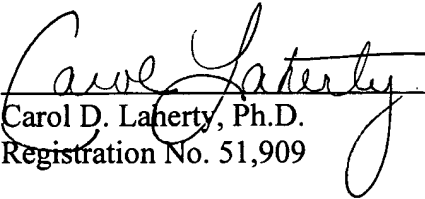
Accordingly, Applicants submit that the specification, as originally filed, discloses specific, substantial, and credible utilities for the claimed invention that would be immediately recognized by the skilled artisan, *e.g.*, the use of the claimed L552S polypeptides in the detection of lung cancer. Applicants respectfully request that the Examiner further consider the additional utilities identified above, in light of the evidence provided by the accompanying Declarations and withdraw this basis of rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 09/519,642
Reply to Office Action dated May 28, 2004

Applicants respectfully submit that all claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants' attorney wishes to express her willingness to engage in a telephone interview to further the status of this application if any further concerns need to be addressed.

Respectfully submitted,
SEED Intellectual Property Law Group PLLC


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CDL:jto

Enclosure:

Postcard
Copy of Fanger Declaration
Copy of Henderson Declaration
Copy of Auto-Reply Facsimile Transmission

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